

# **NCSU IAdvanced Regulatory Science/Affairs in Agriculture**

## **Day 1**

Course introduction (**Keith Edmisten**)

Public policy 101 (**Jayce Sudweeks**)

Public Attitudes, Perceptions, and Engagement in the Field of Genetic Modification (**Jason Delborne**)

## **Day 2 (Scott Shore)**

Convention on Biodiversity (**Scott Shore**)

- a) Cartagena Protocol on Biosafety
- b) Nagoya Protocol
- c) EU & EFSA issues

International regulatory agencies and structures

## **Day 3 (lecturer 1) 3pm to 3:50 (Keith Edmisten & Kristine Kring)**

Traits 102 (Keith Edmisten)

- a) grower acceptance
- b) traits
- c) new technologies (if needed)

Legal aspects (IP and legal) (**Kristine Kring**)

- a. Patent protection
- b. Product (technology) liability
- c. Lifecycle management
- d. Proprietary regulatory studies (data compensation)
- e. Anti-trust laws
- f. Complaints
- g. Ethics/compliance
- h. Business confidentiality

## **Days 4 and 5 (Volker Bornemann/Jessica Fernandez & Friends)** **(Charlotte Sanson from Bayer has offered to help)**

TBD????????????????????????????????

## **Days 6 and 7 (Laura Privalle & Friends) (Dean Bushey, Ali Scott, Michael Weeks from Bayer have offered to help)**

Review the Development Process (all 5 phases)

Conduct a Weight-of- Evidence Allergenicity assessment

- a. Bioinformatics screen activity
- b. Evaluate results of other endpoints (digestive fate, heat stability, History of safe use, source of gene/protein)

Study Design Exercise – Protein expression/Inheritance

- a. Which time points
- b. Which tissues
- c. Number of replicates
- d. Determine exposure (environment vs. consumption)

Conduct a comparative assessment – Agronomic parameters, composition analytes

Using data and statistical analyses provided, evaluate the equivalency of the product

## **Day 8 (Katie Davis)**

- a. Presentation skills
  - a) Maybe present a proposed regulatory package to a mock USDA, EPA, or FDA panel of risk assessors as student groups
- b. Negotiating skills
  - a) Could potentially be tied into the proposed presentation skills activity
  - b) Stakeholders
  - c) Regulatory officials

## **Day 9 & 10 (Scott Kohne)**

**(1 or 2 lectures?)**

1. Brief review lecture from basic course
2. Case study of current corn litigation case (students participate)

**Day 11 (Michael Weeks)**

Hands on exercise - develop a containment protocol for a permit for a novel GE plant

- a. brief presentation on the biology of the plant,
- b. small groups to develop various portions of what we would think the USDA would require for containment (e.g., volunteer management, reproductive isolation, etc.).

**Day 12 (Iian Kelly)**

TBD

**Day 13 & 14 (Chris Hofelt)**

Review: Life of a molecule